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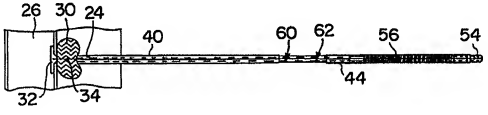


(57) Abstract

A hemostasis promoting device is disclosed for sealing an incision or puncture in the body of a patient wherein the closure device includes an anchor member, a sealing member, a filament member and a spring tensioned tamping member wherein the tamping member is arranged to provide a steady pressure to the sealing member to securely and reliably seal the puncture while including various markers thereon to provide the user with visual indications that the closure device is properly deployed in the puncture and blood vessel of the patient to ensure that the patient may be promptly and reliably ambulated within a relatively short period of time once the closure device has been administered to the patient.

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# HEMOSTATIC PUNCTURE CLOSURE DEVICE

## Field of the Invention

The present invention relates generally to a device to seal openings in the body of a patient and, more particularly, to an improved hemostatic puncture closure device which preferably includes an anchor, collagen member and a spring tensioned insertion and tamping member.

## Background of the Invention

In United States Letters Patent No. 5,021,059 and U.S. Patent No. 5,222,974 granted to Kensey et al. there is disclosed a closure device and method of use for sealing a small incision or puncture in tissue separating one portion of the body of a living being from another portion thereof; e.g., a percutaneous puncture in an artery, to prevent the flow of a body fluid; e.g., blood, through the puncture. The closure device is arranged to be used with and deployed by an instrument which comprises a carrier or delivery instrument in the form of a tubular member. The tubular member has a proximal portion and a distal portion. The distal portion of the tubular member includes an open free end which is arranged to be introduced through the incision or puncture. The proximal portion of the tubular member is arranged to be located externally of the body of the human patient when the distal portion extends through the incision or puncture and into the blood vessel of the patient.

The closure devices of the Kensey patents generally consist of three basic sealing components; namely, an anchor member, a sealing member and a filament; e.g., suture. The sealing member is formed of a hemostatic material; e.g., compressed collagen foam and is configured to engage the tissue adjacent to the puncture. The anchor

member is configured to pass through the puncture in one direction but is resistant to passage therethrough in the opposite direction. The filament is connected between the anchor member and the sealing member in a pulley-like arrangement so that they may be moved relative to each other by the application of a pulling force on the filament.

The delivery instrument is arranged to expel the anchor member through the puncture; e.g., into the artery, and to draw the tissue engaging portion of the anchor member into engagement with the tissue contiguous with the puncture. The filament extends through the instrument to a point outside the body of the patient and is arranged to be drawn in the proximal direction, whereupon the portion of the filament connecting the anchor member and the sealing member causes the tissue engaging portion of the sealing member to move with respect to the anchor member and into engagement with the tissue contiguous with the puncture on the opposite side thereof from the anchor member. This action causes the tissue engaging portion of the sealing member to seal the puncture from the flow of fluid therethrough.

The closure device and deploying instrument disclosed in Patent Nos. 5,021,059 and 5,222,974 may occasionally leave something to be desired from the standpoints of effectiveness and efficiency of use. For example, an initial measurement or locating step is performed to identify the location of the wall of the blood vessel and to ensure that the closure device and distal end of the delivery instrument are properly positioned with respect to the wall of the blood vessel prior to expulsion of the closure member.

Additionally, it is currently necessary to attach a leaf spring or similar type member to the suture between a metal band and the sealing member once the closure device is deployed to apply a constant tension to the closure device for a limited period of time.

Summary of the Invention

Accordingly, it is a general object of this invention to provide a device and methods of use which overcome the disadvantages of the prior art.

It is a further object of this invention to provide a reliable hemostatic puncture closure system including a closure, a deploying instrument and method of use for quickly, easily, safely and effectively sealing a percutaneous puncture in a blood vessel within the body of a living being from another portion.

It is yet another object of the present invention to provide a self contained system which may be used for sealing punctures of various sizes.

These and other objects of this invention are achieved by providing a system for sealing a percutaneous incision or puncture in a blood vessel of a human patient. The system generally includes a procedure sheath, a carrier device and a closure assembly. The puncture comprises a tract extending through tissue overlying a target organ such as a blood vessel. The closure assembly generally includes an anchor member, a sealing member and a filament member. The filament member is connected to the anchor member and passes through the sealing member. The procedure sheath consists of a tubular member having a distal free end arranged to be inserted into the puncture tract and through the puncture. The carrier member is arranged to be inserted through the introducer member to expel the anchor member therefrom and to draw the anchor member into engagement with the distal free end of the procedure sheath and wall of the blood vessel. The procedure sheath and the carrier member are movable together through the incision and into a portion of the blood vessel. The filament member extends from the proximal end of the carrier tube, into the puncture and through the sealing member to the anchor member.

In accordance with one aspect of this invention the carrier device includes a bypass tube, a tamper tube and spring housing and a method of use to enable one to readily seal the puncture while minimizing the steps and manipulation required to position the closure member. In accordance with another aspect of the present invention, the filament member, anchor member and sealing member are positioned in the carrier device and may be tensioned during placement and after placement without the use of extraneous components to effectively seal incisions or punctures of various sizes.

In accordance with another aspect of this invention the system includes various indicators on the carrier device to signal to the user that the anchor member and sealing member have properly deployed in the puncture tract and blood vessel of the patient to reliably seal the puncture.

Brief Description of the Drawings

Other objects and many of the attendant advantages of this invention will readily be appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

Figure 1 is a diagrammatic view, partially in cross section, of the assembled carrier device and closure device of the present invention;

Figure 2 is an enlarged side view, partially in cross section, showing the bypass tube of the present invention;

Figure 3 is an enlarged side view, partially in cross section, showing the tamper tube of the present invention;

Figure 4 is an enlarged side view, partially in cross section, showing the spring housing of the present invention;

Figure 5 is an enlarged side view, partially in cross section, showing the assembled closure device positioned in the bypass tube of the present invention;

Figure 6 is an enlarged side view, partially in cross section, showing the assembled proximal end portion of the tamper tube and the spring housing of the present invention;

Figure 7 is an enlarged side view, partially in cross section, showing the carrier device and closure device aligned with the introducer sheath of the present invention;

Figure 8 is an enlarged side view, partially in cross section, showing the bypass tube of carrier device of the present invention initially positioned within the introducer sheath;

Figure 9 is an enlarged side view, partially in cross section, showing the tamper tube of carrier device of the present invention initially moved further distally within the introducer sheath;

Figure 10 is an enlarged side view, partially in cross section, showing the tamper tube and spring housing of carrier device of the present invention twisted with respect to each other to release the pin from the groove and activate the tension of the spring member on the anchor member;

Figure 11 is an enlarged side view, partially in cross section, showing the advancement of the tamper tube of carrier device of the present invention to expel the anchor member from the introducer sheath and expose the stop marker on the tamper tube;

Figure 12 is an enlarged side view, partially in cross section, showing the proximal movement of the carrier device of the present invention in the puncture to cause the engagement of the anchor member along the wall of the blood vessel;

Figure 13 is an enlarged side view, partially in cross section, showing the tamper tube and spring housing of

Figure 12 with the introducer sheath and bypass tube removed from the puncture;

Figure 14 is an enlarged side view, partially in cross section, showing the tamper tube and spring housing of the present invention with the second marker on the tamper tube exposed; and

Figure 15 is an enlarged side view, partially in cross section, showing the closure device of the present invention deployed in the puncture and blood vessel of the patient.

Detailed Description of the Preferred Embodiment

Referring now in greater detail to the various figures of the drawings wherein like reference characters refer to like parts, there is shown at 20 a carrier device forming a portion of a system for deploying a closure device 22 to seal a percutaneous puncture 24 within a blood vessel 26; e.g., the femoral artery, constructed in accordance with this invention. The puncture 24 includes not only the opening in the wall of the vessel but also the tract; i.e., the passageway in the tissue located between the vessel and the skin of the human patient which is formed when the vessel is punctured. As used herein, the distal end of an element is referred to as the end of the element nearest to the patient and the proximal end of an element is referred to as the element furthest from the patient.

The carrier device 20 and closure device 22 have particular utility when used in connection with various intravascular procedures, such as angiography, cardiac catheterization, balloon angioplasty and other types of cardiovascular procedures, etc. since the closure device 22 is designed to cause immediate hemostasis of the blood vessel; e.g., arterial, puncture. However, it is to be understood that while the description of the preferred embodiment instrument and closure contained herein is directed to the closure of percutaneous incisions or

punctures in arteries, they have much more wide-spread applications, wherein it is desirable to close an opening in the body of the patient. Thus, the sealing of a percutaneous opening in an artery shown herein is intended to be merely exemplary.

Before describing the closure device 22 and the carrier device 20 for inserting it to seal the opening, a brief description of a typical, conventional, intravascular surgical procedure; e.g., catheter instrumentation of an artery, utilizing a percutaneous opening will be given to best appreciate the features of the invention. In such a procedure a cannula of an instrument, such as an angiographic needle (not shown), is inserted percutaneously through the skin into the artery, such as the femoral artery, at the site of the instrument's insertion. The needle cannula is held in place, and the flexible end of a guide wire (not shown) is then passed through the cannula into the artery to the desired depth (i.e., longitudinal position therealong). Once the guide wire is in place, the needle cannula is removed, leaving the guide wire in place. An introducer sheath 28 and an arterial dilator (not shown) are then passed over the guide wire, through the puncture or incision and into the artery. The guide wire and then the dilator are removed leaving the introducer sheath in place. A catheter, or other intravascular instrument (not shown) is then inserted through the introducer sheath 28 and threaded down the artery 26 to the desired intravascular location; e.g., the site of the atherosclerotic occlusion.

Once the intravascular procedure (e.g., angiography, angioplasty or stent placement) has been completed, the catheter is removed. Thereafter, the sheath is removed and the surgeon or other trained person previously applied manual, digital pressure to the percutaneous puncture until hemostasis occurred. The standard of care for puncture hemostasis for many years was to apply digital or mechanical pressure on the puncture site for twenty minutes

to an hour, depending on the puncture size and the degree of anticoagulant therapy. Obviously, this resulted in a significant amount of wasted time for the physicians and other catheter lab personnel and caused unnecessary inconvenience and discomfort for the patient. In addition, serious complications may arise from persistent bleeding and hematoma formation.

In accordance with the preferred method of use of this invention, the introducer sheath 28 remains in the artery and is moved so that its distal end is at a desired position therein, as will be described. Figures 7-14 are illustrations showing the sequential steps in the use of the carrier device of the present invention to deploy the closure device to seal the percutaneous puncture in the blood vessel of the human or animal patient. The carrier device 20 having the closure device 22 therein is initially inserted into the introducer sheath. The closure device is then deployed (ejected) and operated to immediately seal the arterial puncture site 24 and plug the tract. Moreover, as will be appreciated from the description to follow, the closure device 22 is designed to reduce post-procedure puncture complications, cause minimal inflammatory reaction and resorb completely within a relatively short period of time; e.g., sixty to ninety days.

The sealing member 30 is preferably formed as a cylindrical member which is made of a compressible, resorbable hemostatic or clot promoting material such as collagen. The sealing member 30 is initially compressed from a larger diameter configuration to a smaller diameter, elongated member which is inserted into the carrier device 20. The preferred diameter of the sealing member is relatively small, e.g. about 2.52 mm to be suitable for use within a carrier device which has an outer diameter of between about 4 french to 10 french depending on the size of the insertion sheath used in the procedure.

The anchor member 32 basically comprises a thin, narrow strip or bar of a resorbable and preferably moldable material such as a resorbable lactide/glycolide polymer manufactured and sold by various companies such as Medisorb Technologies International L.P. under the trade designation MEDISORB. The strip is sufficiently rigid such that once it is in the desired position in the artery (as will be described later) it is relatively resistant to deformation to preclude it from accidentally bending or folding and passing back through the puncture through which it was first introduced. The anchor member 32 preferably has a generally planar top and bottom surface and a peripheral side surface. Each end of the anchor member 32 is rounded. The top surface of the anchor member preferably includes the end of the filament member molded therein or tied thereon. Alternately, a longitudinally extending slot may be formed in the anchor member and disposed perpendicularly to the top surface of the anchor member 32. A portion of a positioning or filament member 34 may then be threaded therethrough. In the form of the sealing member wherein the filament member 34 is threaded therethrough, a portion of the filament member 34 is threaded through a slot in the anchor member 32 and back out of the slot on the other side thereof. The filament member is then preferably tied in a knot near the proximal end portion of the sealing member 30 to connect the sealing member 30 to the anchor member 32.

The filament member 34 of the closure device 22 serves to interconnect the sealing member 30 and the anchor member 32 and to assist in the movement of the sealing member 30 toward the anchor member 32, once the anchor member 32 is in its desired position in the artery adjacent to the puncture. In accordance with a preferred embodiment of this invention, the filament member 34 or filament is formed of resorbable, flexible material such as a resorbable suture.

As can be seen in the drawings, the carrier device 20 is preferably formed of a somewhat flexible material, such

as polyethylene or TEFLON, so that the carrier device 20 may be freely passed through the introducer sheath 28 into an operative position within the patient's artery, notwithstanding any slight curvature or bending of the introducer sleeve which may exist through the puncture or artery. The outside diameter of the carrier device 20 is preferably between about 6 to 12 French to conform with the size of the punctures formed by the majority of procedures and introducer sheaths. The carrier device 20 generally consists of an elongate and cylindrical tamper tube 40 and a shorter, cylindrically shaped bypass tube 42 slidably mounted on the distal end of the tamper tube 40. A spring housing 44 is provided along the proximal end of the tamper tube 40. The use of the bypass tube 42 enables the carrier device 20 to be inserted through a conventional hemostasis valve (not shown) formed on the proximal end portion of the introducer sheath 28 without damaging the closure device 20 of the present invention. The length of the tamper tube 40 is preferably chosen so that the distance between the distal end portion of the tamper tube 40 and a shoulder surface 48 thereon is sufficient to expel the anchor member 32 of the closure device from the distal end of the introducer sheath 28.

The closure device 22 is preferably preloaded within the bypass tube 42 of the carrier device 20 and is positioned distally of the tamper tube 40. As shown, the anchor member 32 is preferably oriented longitudinally within the distal end portion of the bypass tube 42 and is positioned laterally of the central longitudinal axis of the carrier device 20. The sealing member 30 is located within the majority of the bypass tube 42 and just behind (proximally) the anchor member 32. The sealing member preferably fills the entire longitudinal cross section of the bypass tube 42. The filament member 34 extends from the anchor member 32, through the longitudinal axis of the sealing member 30 and tamper tube 40 and to the proximal end of the spring housing 44 where it is engaged by a

suture lock 54. The bypass tube 42 may also include reference wings 46 or detents (not shown) along its periphery. The reference wings 46 serve as a visual guide to help the user orient the carrier device 20 to a proper yaw angle with respect to the introducer sheath 28 as will be described later.

The distal end of the tamper tube 40 slidably fits within the proximal end portion of the bypass tube 42 and is in contact with the sealing member 30 of the closure device 22. The proximal end of the tamper tube 40 extends into an opening in the distal end portion of the spring housing 44 and includes an outer circumferential shoulder surface 48 on the proximal end portion thereof. The tamper tube 40 is movably secured to the spring housing 44 by any suitable means, including the pin 50 and groove 52 arrangement shown in the preferred form of the present invention. In the preferred embodiment of the present invention, the length of the groove is preferably the same as or longer than the length of the anchor member 32 and sealing member 30. A tension force is generated by the interaction of the tamper tube 40 and the spring housing 44. A preferably coiled and compressed spring 56 is located within the spring housing 44. The suture lock 54 is fixedly attached to the proximal end of the spring housing 44 and contacts the proximal end of the coiled spring 56 to maintain the desired tension and compression in the coiled spring 56. The distal end of the coiled spring 56 is preferably in contact with the proximal end of the tamper tube. As will be appreciated by those skilled in the art, the tensioning assembly just described is intended to provide a predetermined amount of tension on the filament member 34 and may be actuated by various methods, including the relative rotation of a pair of members, a latch or button release mechanism or other available methods to actuate the tensioning assembly as desired by the user.

The preferred method of use for the present invention includes the initial step of positioning the distal end introducer sheath 28 in the artery a short distance beyond the wall of the blood vessel. This may be accomplished in a variety of ways, including through the use of an artery locator device as disclosed in U.S. Patent No. 5,222,974. After the introducer sheath is properly positioned in the artery, the introducer sheath 28 must be kept fixed with respect to the skin and blood vessel of the patient.

The physician initially grasps and fully inserts the bypass tube 42 portion of the carrier device 20 into the previously positioned introducer sheath 28. On complete insertion of the bypass tube 42 into the introducer sheath 28, the tamper tube 40 is advanced further into the introducer sheath 28 so that the anchor member 32 of the closure device 22 is positioned a short distance proximally of the distal end of the introducer sheath 28. As shown in Figure 10, the tamper tube 40 and spring housing 44 are grasped and twisted with respect to each other to release the tension lock created by the groove 52 and pin 50 to release the compression on the coiled spring 56 such that the pin 50 is moved from the proximal locked portion of the groove 52 to the distal portion of the groove 52. The release of the compression on the coiled spring 56 tensions the filament member 34 between the suture lock 54 and the anchor member 32 in the bypass tube 42. The tamper tube 40 is then grasped and moved distally with respect to the bypass tube 42 and introducer sheath 28 to move the anchor member 32 out of the distal end of the introducer sheath 28. Because the filament member 34 is tensioned by the coiled spring 56, as the anchor member 32 passes beyond the distal end of the introducer sheath 28 it is automatically toggled and deploys into the blood vessel generally adjacent to the wall of the artery and puncture. The application of the tension on the anchor member 32 also causes the spring housing 44 to move proximally with respect to the tamper tube 40 to expose a stop marker 60 on

the body of the tamper tube 40 when the anchor member 32 is deployed. The stop marker 60 provides a positive indication to the user that the anchor member has been deployed. The user then withdraws the carrier device 20 with respect to the introducer sheath 28 and bypass tube 40 until resistance is encountered. The existence of resistance to continued withdrawal indicates that the anchor member 32 has engaged the wall of the blood vessel.

The introducer sheath 28 and bypass tube 42 are then removed from the puncture by passing the introducer sheath 28 and bypass tube 42 over the tamper tube 40 and spring housing 44. As the introducer sheath 28 and bypass tube 42 are removed, the coiled spring 56 continues to apply a tamping force to the closure device 22. The distal end portion of the tamping tube 40 pushes against the proximal end of the sealing member 30 so that as the sealing member 30 absorbs fluids from the surrounding tissue and softens, the sealing member 30 is transformed from the generally cylindrical configuration it formed when it was positioned in the tamper tube 30 to a more bulbous and malleable shape which conforms to the tissue surrounding the puncture. As the sealing member 30 softens and presses against the tissue adjacent to the blood vessel, the tamping member 40 gradually moves distally in the puncture and the coiled spring 56 in the spring housing 44 causes relative movement between the tamper tube 40 and the spring housing 44 so that a second marker 62 is exposed on the outer surface of the tamper tube 40. Exposure of this second marker 62 indicates to the user that the sealing member 30 of the closure device 22 has been compressed sufficiently by the continued tension on the filament member 34 to provide reliable closure of the puncture. If desired, a few gentle compactions with the tamper tube 40 may also be applied to assist the sealing member 30 to conform to the tissue adjacent to the puncture and to assist in the frictional engagement of the filament member 34 by the sealing member 30. It is believed that initial hemostasis occurs very

quickly, thereby locking the closure device 20 in position in the puncture. It should be noted that during this additional tamping action care must be taken to maintain tension on the filament member 34 at a load equal to or greater than that used on the tamper member 40 to ensure that the tamping action doesn't propel the sealing member 30 into the interior of the blood vessel.

Once the second marker 62 is visible, the user may then cut, clip or otherwise cause the suture lock 54 to release the filament member 34. When the filament member has been released from the suture lock 54, the tamper tube 40 and spring housing 44 may be removed and then the filament member 34 may be cut at the skin level of the patient. The closure device 22 is now initially locked in place through the clotting of the hemostatic sealing member 30 and by tension between the sealing member 30 and the anchor member 32 as well as the interaction between the sealing member 30 and the tissue surrounding the puncture. Thus the artery wall is sandwiched between the sealing member 30 and the anchor member 32. Within a few hours after deployment, the anchor member 32 will typically be coated with fibrin and thus attached firmly to the arterial wall, thereby eliminating the possibility of distal embolization. After approximately thirty days, only a small deposit of anchor material will remain. In fact, resorption of all components will have typically occurred after approximately sixty days.

As should also be appreciated from the foregoing, the closure device, the carrier device for deploying it and their method of use enables the ready, effective and efficient sealing of a percutaneous puncture in an artery. Thus, it is expected that the present hemostatic puncture closure device will be a significant advancement in the fields of cardiology and radiology. The present device may allow continuance of anticoagulation post-procedure, more aggressive use of thrombolytic agents and safer use of large bore catheters. It should also reduce discomfort and

complication rates for patients, allow many in-patient procedures to be performed safely on an out-patient basis, decrease the time and cost of interventional procedures and reduce exposure of hospital personnel to human blood.

Without further elaboration, the foregoing will so fully illustrate our invention that others may, by applying current or future knowledge, adopt the same for use under various conditions of service.

Claims

What is claimed is:

1. An assembly for sealing an incision or puncture in the body of a patient wherein the puncture extends from the skin of the patient into a blood vessel, duct or lumen of the patient, the assembly comprising:

a first member formed of a bioabsorbable material and sized to be positioned in the blood vessel, duct or lumen of the patient;

a second member formed of a bioabsorbable material and said second member cooperatively seals the puncture from the flow of fluids therethrough in combination with said first member;

a third member formed of a bioabsorbable material and including a portion thereof which is positioned to extend proximally of said first member and said second member in the puncture;

a carrier device including a tensioning member formed as a part thereof, and said carrier device including said first member, said second member and said third member therein; and

said tensioning member operatively connected to said third member to apply tension to said third member and cause said first member to contact the wall of the blood vessel, duct or lumen upon deployment of said first member and said second member from said carrier device.

2. The assembly of claim 1 wherein said assembly further includes a tamper member and said tensioning member applies compression forces to said tamper member to cause said second member to move distally in the puncture towards said first member.

3. The assembly of claim 1 wherein said third member is a filament member extending proximally from said first member and through said second member.

4. The assembly of claim 3 wherein said filament member is threaded through said second member and said filament member is frictionally engaged with at least one of said first member, second member or said tensioning member.

5. The assembly of claim 3 wherein carrier device further includes a tamper member and said filament member is slidable through said tamper member.

6. The assembly of claim 1 further including an elongate tamper member wherein said third member is threaded therethrough.

7. The assembly of claim 1 further including a spring housing wherein said tensioning member is retained therein.

8. The assembly of claim 7 wherein said third member is threaded through at least a portion of said spring housing.

9. The assembly of claim 1 further including an elongate spring housing and an elongate tamper member wherein said tensioning member is retained in said spring housing and is oriented to cause the distal movement of said tamper member with respect to said spring housing.

10. The assembly of claim 9 wherein rotation of said spring housing with respect to said tamper member causes the application of a force to said tamper member and said

tamper member is moved distally in the puncture in contact with said second member.

11. The assembly of claim 1 wherein said carrier device further includes an elongate spring housing and an elongate tamper member wherein said spring housing and said tamper member are oriented with respect to each other to have a first elongate length and said tensioning member is retained in said spring housing and is oriented to permit the movement of said spring housing and said tamper member to a second elongate length which is greater than said first elongate length.

12. The assembly of claim 11 wherein movement of said spring housing and said tamper member from said first elongate length to said second elongate length is caused by a release of compression on said tensioning member.

13. The assembly of claim 12 wherein rotation of said spring housing and said tamper member with respect to each other permits said release of compression on said tensioning member.

14. An assembly for sealing an puncture in the body of a human patient wherein the puncture extends from the skin of the patient into a blood vessel of the patient, the assembly comprising:

a first member formed of a bioabsorbable material and sized to be positioned in the blood vessel of the patient;

a second member formed of a bioabsorbable and hemostasis promoting material and said second member cooperatively seals the puncture from the flow of fluids therethrough;

an elongate and flexible positioning member movable with respect to said second member and said

positioning member being in connective engagement with said first member; and

a carrier device including a spring member therein and said spring member is arranged to apply tension to said positioning member and cause said first member to contact the wall of the blood vessel adjacent to the puncture.

15. The assembly of claim 14 wherein said carrier device further includes a tamper member and a spring housing wherein said positioning member is threaded through at least a portion of said tamper member and said spring member is contained in said spring housing.

16. The assembly of claim 15 wherein said spring member is compressed in at least one of said spring housing and said tamper member in a first elongate length of said spring housing and said tamper member and substantially uncompressed in a second elongate length of said spring housing and said tamper member.

17. The assembly of claim 16 wherein said second elongate length of said spring housing and said tamper member is greater than said first elongate length of said spring housing and said tamper member.

18. The assembly of claim 15 wherein said spring housing and said tamper member are rotatable with respect to each other to permit the movement of said spring housing and said tamper member from a first elongate length to a second elongate length wherein said first elongate length is different from said second elongate length.

19. The assembly of claim 16 wherein said tamper member facilitates the distal movement of said second member in the puncture when said spring housing and said tamper member are in said second elongate length.

20. An assembly for sealing an incision or puncture in the body of a patient wherein the puncture extends from the skin of the patient into a blood vessel, duct or lumen of the patient, the assembly comprising:

a first member formed of a bioabsorbable material and sized to be positioned in the blood vessel, duct or lumen of the patient;

a second member formed of a bioabsorbable material and said second member cooperatively seals the puncture from the flow of fluids therethrough in combination with said first member;

a third member formed of a bioabsorbable material and positioned in the puncture to extend proximally from said first member;

an elongate housing formed by a spring housing and a tamper member wherein said housing includes said third member threaded through at least a portion thereof; and

a spring member contained in said housing and said spring member being movable between compressed and uncompressed states such that the length of said housing is increased when said spring is moved from said compressed state to said uncompressed state.

21. The assembly of claim 20 wherein rotation of said tamper member with respect to said spring housing permits said spring member to be moved from said compressed state to said uncompressed state.

22. The assembly of claim 20 wherein said tamper member applies distally directed pressure to said second member in the puncture when said spring member is in said uncompressed state.

23. A method of sealing a puncture formed in the body of a patient wherein the puncture extends generally from the skin of a patient into a selected blood vessel of the patient, the method comprising:

inserting a carrier device into the puncture to deliver a closure device to a location generally adjacent to the wall of the blood vessel;

expelling the closure device from the carrier device to insert the closure device having first, second and third members into the puncture such that the second member is positioned in the puncture proximally of the first member to seal the puncture from the flow of blood passing through the blood vessel and the third member extends proximally from said first member and through said second member; and

actuating a portion of the carrier device such that the length of the carrier device is increased and tension is applied to the third member by the actuated carrier device.

24. The method of claim 23 further including the step of tamping the second member with at least a portion of the carrier device once the length of the carrier device has been increased until hemostasis is achieved in the puncture in the body of the patient.

25. The method of claim 23 further including the step of ejecting the first member into the blood vessel and sliding the second member along the third member wherein the third member consists of a filament member.

26. The method of claim 23 further including the step of rotating a first portion of the carrier device with respect to a second portion of the carrier device to cause an increase in the length of the carrier device and permit the distal movement of the second member in the puncture to obtain hemostasis in the puncture of the patient.

27. The method of claim 23 further including the step of providing a carrier device having a spring housing portion and a tamper member portion and rotating the spring housing with respect to the tamper member to cause the relaxation of a spring member thereby permitting an increase in the length of the carrier device.

28. The method of claim 23 further including the step of providing a spring member in the carrier device wherein the spring member is in a compressed state during the insertion of the carrier device and delivery of the closure device and wherein upon release of the spring member from the compressed state, the tamper member applies pressure to the second member in the puncture.

29. The method of claim 23 further including the step of removing the carrier device from the puncture once hemostasis has been obtained in the puncture by the closure device.

30. A method of sealing a puncture formed in the body of a patient wherein the puncture extends generally from the skin of a patient into a selected blood vessel of the patient, the method comprising:

inserting a carrier device into an introducer sheath located in the puncture of a patient to deliver a closure device to a location generally adjacent to the wall of the blood vessel wherein the insertion step includes inserting a bypass sheath from the carrier device into the introducer sheath;

actuating a portion of the carrier device such that the length of the carrier device is increased and a force is applied to at least a portion of the closure device by the actuated carrier device;

inserting at least a portion of the closure device into the puncture and blood vessel until an observable indicator on the carrier device is observed; and

applying a distal force to the closure device with at least a portion of the carrier device until an observable indicator is observed indicating that tamping has been completed.

31. The method of claim 30 wherein the step of actuating a portion of the carrier device includes the step of rotating a first portion of the carrier device with respect to a second portion of the carrier device.

32. The method of claim 30 wherein the step of actuating a portion of the carrier device includes the step of releasing a spring member from a compressed state to a less compressed state.

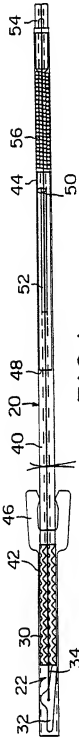


FIG. 1


FIG. 4


FIG. 2


FIG. 3

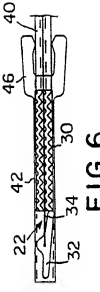


FIG. 6

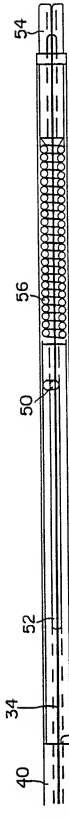


FIG. 7


FIG. 5B




FIG. 5C


FIG. 5A

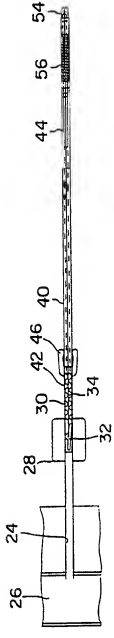


FIG. 8

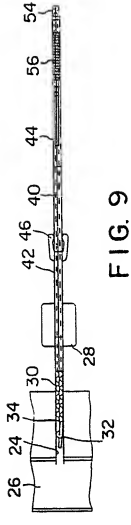


FIG. 9

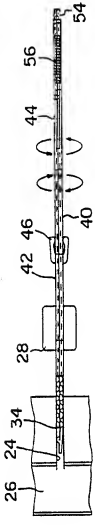


FIG. 10

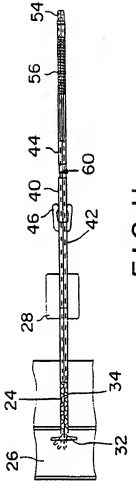


FIG. 11

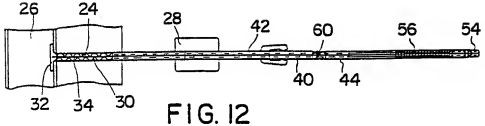


FIG. 12

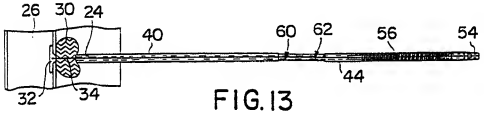


FIG. 13

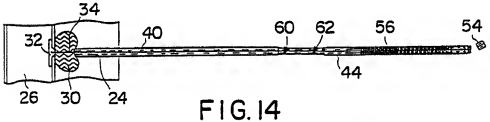


FIG. 14

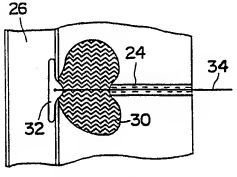


FIG. 15

# INTERNATIONAL SEARCH REPORT

| International Application No |
|---|
| PCT/US 98/23102 |

**A. CLASSIFICATION OF SUBJECT MATTER**
IPC 6 A61B17/00

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | US 5 021 059 A (KENSEY ET AL.) 4 June 1991<br>cited in the application<br>see the whole document | 1,14,20 |
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☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 29 January 1999 | 08/02/1999 |

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (+31-70) 340-3016 | Giménez Burgos, R |

Form PCT/ISA/210 (second sheet) (July 1992)

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/ 23102

**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 23-32
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

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Information on patent family members

International Application No
PCT/US 98/23102

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Information on patent family members

International Application No
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